AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application.

Listing of Claims

1-35. (Canceled)

36. (Currently Amended) An apparatus for applying a physiologically active agent or prodrug thereof to a dermal surface or mucosal membrane of an animal, said apparatus comprising (A) a container and, in said container, (B) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises:

(1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof ~~; (ii)~~ **and** at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and

(2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface or mucosal membrane of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface or membrane and (ii) is of low toxicity to and is tolerated by the dermal surface or mucosal membrane of the animal, and wherein, after application of the system to an area of the dermal surface or mucosal membrane, the area becomes touch-dry within three minutes of application.

37. (Previously Presented) The apparatus of claim 36, wherein the dermal penetration enhancer is one or more esters selected from the group consisting of C_8 to C_{18} alkyl para-aminobenzoate, C_8 to C_{18} alkyl dimethyl-para-aminobenzoate, C_8 to C_{18} alkyl cinnamate, C_8 to C_{18} alkyl methoxycinnamate and C_8 to C_{18} alkyl salicylate.

38. (Previously Presented) The apparatus of claim 36, wherein the container further comprises a pharmaceutical-grade spray nozzle.

39. (Previously Presented) The apparatus of claim 38, wherein the container is an aerosol container that contains a propellant for dispensing the drug delivery system as an aerosol.

40. (Previously Presented) The apparatus of claim 38, wherein the container further comprises a shroud that is configured (A) to maintain the nozzle at a predetermined height above and perpendicular to the dermal surface or mucosal membrane and (B) to enclose the area between the nozzle and the dermal surface or mucosal membrane.

41. (Previously Presented) The apparatus of claim 40, wherein the shroud defines an area on the dermal surface or mucosal membrane that is substantially circular in shape.

42. (Previously Presented) The apparatus of claim 56, wherein the apparatus provides one or more metered doses of the drug delivery system.

43. (Previously Presented) The apparatus of claim 56, wherein the apparatus comprises a pharmaceutical grade metered dose valve.

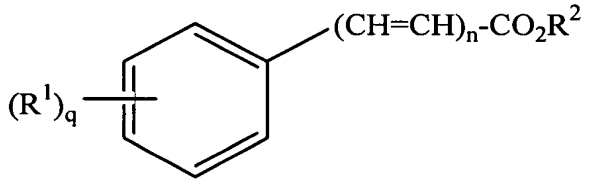
44. (Previously Presented) The apparatus of claim 56, wherein the apparatus provides one or more fixed metered doses of the drug delivery system.

45. (Canceled)

46. (Previously Presented) The apparatus of claim 56, wherein the dermal surface or mucosal membrane becomes touch-dry within 1 minute of application of the drug delivery system.

47. (Previously Presented) The apparatus of claim 36, wherein the dermal penetration enhancer is a safe skin tolerant sunscreen.

48. (Previously Presented) The apparatus of claim 36, wherein the dermal penetration enhancer is an ester of formula (I):



(I)

wherein R^1 is hydrogen, lower alkyl, lower alkoxy, halide, hydroxy or NR^3R^4;

R^2 is a long chain alkyl;

R^3 and R^4 are each independently hydrogen, lower alkyl or R^3 and R^4 together with the nitrogen atom to which they are attached form a 5- or 6-membered heterocyclic ring;

n is 0 or 1; and

q is 1 or 2.

49. (Previously Presented) The apparatus of claim 36, wherein the dermal penetration enhancer is one or more esters selected from the group consisting of a long chain alkyl para-aminobenzoate, long chain alkyl dimethyl-para-aminobenzoate, long chain alkyl cinnamate, long chain alkyl methoxycinnamate and long chain alkyl salicylate.

50. (Previously Presented) The apparatus of claim 49, wherein the dermal penetration enhancer is one or more esters selected from the group consisting of octyl dimethyl-para-aminobenzoate, octyl para-methoxycinnamate and octyl salicylate.

51. (Previously Presented) The apparatus of claim 36, wherein the volatile liquid is ethanol or isopropanol.

52. (Previously Presented) The apparatus of claim 36, wherein the physiologically active agent is a steroid, hormone derivative, non-steroidal anti-inflammatory drug, opioid analgesic, antinauseant, antioestrogen, aromatase inhibitor, 5-alpha reductase inhibitor, anxiolytic, prostaglandin, anti-viral drug, anti-migraine compound, antihypertensive agent, anti-malarial compound, bronchodilator, anti-depressant, anti-Alzheimer's agent, neuroleptic and antipsychotic agent, anti-Parkinson's agent, anti-androgen or anorectic agent.

53. (Previously Presented) The apparatus of claim 36, wherein the physiologically active agent is testosterone, oestradiol, ethinyloestradiol, progesterone, norethisterone acetate, ibuprofen, ketoprofen, flurbiprofen, naproxen, diclofenac, fentanyl, buprenorphine, scopolamine, prochlorperazine, metochlopramide, ondansetron, tamoxifen, epitiostanol, exemestane, 4-hydroxy-androstenedione and its derivatives, finasteride, turosteride, LY191704, MK-306, alprazolam, alprostadil, prostacylcin and its derivatives, melatonin, n-docosanol, tromantadine, lipophilic pro-drugs of acyclovir, low molecular weight heparin, enoxaparin, sumatriptan, amlodipine, nitrendipine, primaquine, minoxidil, minoxidil pro-drugs, pilocarpine, salbutamol, terbutaline, salmeterol, ibogaine, bupropian, rolipram, tacrine, fluphenazine, haloperidol, N-0923, cyproterone acetate or mazindol.

54. (Previously Presented) The apparatus of claim 36, wherein the drug delivery system further comprises one or more components selected from the group consisting of a pharmaceutical compounding agent, co-solvent, surfactant, emulsifier, antioxidant, preservative, stabiliser, diluent, and mixtures of two or more of said components.

55. (Previously Presented) An apparatus for applying a physiologically active agent or prodrug thereof through a body surface of an animal, which apparatus comprises a container that contains a pharmaceutical formulation comprised of (i) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and (ii) at least one dermal penetration enhancer and at least one volatile liquid which, in combination, enable the formulation to dry within three minutes of application to the body surface and to provide for transport of the active agent or prodrug during and/or subsequent to drying.

56. (Currently Amended) An apparatus for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising:

(A) a container,

(B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a ~~material~~ **manual** metered dose pump,

wherein said container contains

(C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises:

(1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof~~; (ii)~~ **and** at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and

(2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and

wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application.

57. (Previously Presented) The apparatus of claim 56, wherein the dermal penetration enhancer is one or more esters selected from the group consisting of C_8 to C_{18} alkyl para-aminobenzoate, C_8 to C_{18} alkyl dimethyl-para-aminobenzoate, C_8 to C_{18} alkyl cinnamate, C_8 to C_{18} alkyl methoxycinnamate and C_8 to C_{18} alkyl salicylate.

58. (Previously Presented) The apparatus of claim 56, wherein the container further comprises a pharmaceutical grade spray nozzle.

59. (Previously Presented) The apparatus according to claim 56, wherein the dermal penetration enhancer is selected from the group consisting of C_8 to C_{18} alkyl methoxycinnamate and C_8 to C_{18} alkyl salicylate.

60. (Previously Presented) The apparatus according to claim 56, wherein, the volatile liquid is selected from the group consisting of ethanol and isopropanol.

61. (Currently Amended) ~~The~~ An apparatus ~~of claim 56,~~ for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising:

(A) a container,

(B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump,

wherein said container contains

(C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises:

(1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and

(2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal,

wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application, and

wherein the physiologically active agent is selected from the group consisting of steroids, hormone derivatives, non-steroidal anti-inflammatory drugs, opioid analgesics, antinauseants, antioestrogens, aromatase inhibitors, 5-alpha reductase inhibitors, anxiolytics, protasglandins, anti-viral drugs, anti-migraine compounds, antihypertensive agents, anti-malarial compounds, bronchodilators, anti-depressants, anti-Alzheimer's agents, neuroleptic and antipsychotic agents, anti-Parkinson's agents, anti-androgens and anorectic agents.

62. (Currently Amended) ~~The~~ An apparatus ~~according to claim 56,~~ for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery

system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising:

(A) a container,

(B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump,

wherein said container contains

(C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises:

(1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and

(2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and

wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application, and

wherein the physiologically active agent is a hormone for contraception.

63. (Currently Amended) ~~The~~ An apparatus ~~according to claim 62,~~ for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising:

(A) a container,

(B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump,

wherein said container contains

(C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises:

(1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and

(2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and

wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application, and

wherein the physiologically active agent comprises a progestogen other than progesterone.

64. (Currently Amended) ~~The~~ An apparatus ~~according to claim 62,~~ for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising:

(A) a container,

(B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump,

wherein said container contains

(C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises:

(1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and

(2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and

wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application, and

wherein the physiologically active agent comprises an oestrogen and a progestogen other than progesterone.

65. (Currently Amended) ~~The~~ An apparatus ~~according to claim 62,~~ for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising:

(A) a container,

(B) a metered dose applicator selected from the group consisting of a metered dose aerosol, a stored energy metered dose pump, and a manual metered dose pump,

wherein said container contains

(C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises:

(1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof; and

(2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically

active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal surface of the animal, and

wherein, after application of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application, and

wherein the active agent comprises at least one active agent selected from the group consisting of oestradiol, oestriol, oestrone, ethinyloestradiol, mestranol, stilboestrol, dienoestrol, epioestriol, estropipate, zeranol, progesterone, allyloestrenol, dydrogesterone, lynoestrenol, norgestrel, norethyndrel, norethisterone, norethisterone acetate, gestodene, levenorgestrel, medroxyprogesterone and megestrol.

66. (New) An apparatus for applying a metered dose of a non-occlusive percutaneous or non-occlusive transdermal drug delivery system comprising a physiologically active agent or prodrug thereof to a dermal surface of an animal, comprising:

(A) a container,

(B) a metered dose applicator selected from a metered dose aerosol, a stored energy metered dose pump and a manual metered dose pump,

wherein said container contains

(C) a non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises:

(1) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt% based on the weight of the active agent or prodrug thereof; and

(2) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer,

wherein the physiologically active agent comprises an oestrogen, and

wherein the dermal penetration enhancer (i) is adapted to transport the physiologically active agent across a dermal surface of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface and (ii) is of low toxicity to and is tolerated by the dermal

surface of the animal, and wherein, after application of a metered dose of the system to an area of the dermal surface, the area becomes touch-dry within three minutes of application.